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| APPLICATION NO.                | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |  |
|--------------------------------|-----------------|----------------------|-------------------------|------------------------|--|
| 09/507,613                     | 02/21/2000      | James G. Whayne      | 15916-229x              | 1854                   |  |
| 21836 7                        | 7590 01/13/2004 |                      | EXAMI                   | EXAMINER               |  |
| HENRICKS SLAVIN AND HOLMES LLP |                 |                      | RODRIGUEZ, C            | RODRIGUEZ, CRIS LOIREN |  |
| SUITE 200<br>840 APOLLO        | STREET          |                      | ART UNIT                | PAPER NUMBER           |  |
| EL SEGUNDO                     | O, CA 90245     |                      | 3763                    |                        |  |
|                                |                 |                      | DATE MAILED: 01/13/2004 | V                      |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| • 1   |  |   |  | 1 |  |  |  |
|---|--|---|--|---|--|--|--|
|   |  | Application No.   | Applicant(s)   |   |  |  |  |
| Office Action Summary   |  | 09/507,613  | WHAYNE ET AL.  |   |  |  |  |
|   |  | Examiner  | Art Unit   |   |  |  |  |
|   |  | Cris L. Rodriguez   | 3763   |   |  |  |  |
| Period fo   | The MAILING DATE of this communication apported in Reply   | pears on the cov r sheet with the c   | correspond nc addr ss  |   |  |  |  |
| THE  <br>- Exte<br>after<br>- If the<br>- If NC<br>- Failu<br>- Any I | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).   | 136(a). In no event, however, may a reply be tin<br>by within the statutory minimum of thirty (30) day<br>will apply and will expire SIX (6) MONTHS from<br>to, cause the application to become ABANDONE  | nely filed rs will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).                                  |   |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on 10 C   | October 2003.   |  |   |  |  |  |
| 2a) <u></u> □   | This action is <b>FINAL</b> . 2b)⊠ This  | action is non-final.  |  |   |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |  |   |  |  |  |
| Disposit  | ion of Claims  |   |  |   |  |  |  |
| 5)□<br>6)⊠<br>7)⊠   | Claim(s) 10-37 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 10-13 and 15-37 is/are rejected.  Claim(s) 14 is/are objected to.  Claim(s) are subject to restriction and/or election requirement.  |   |  |   |  |  |  |
| ŕ   | ion Papers   |   |  |   |  |  |  |
| 10)   | The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine The specific and the spe | cepted or b) objected to by the drawing(s) be held in abeyance. Settion is required if the drawing(s) is ob   | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).   |   |  |  |  |
| Priority (  | under 35 U.S.C. §§ 119 and 120   |   |  |   |  |  |  |
| * (\$<br>13)  | Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea See the attached detailed Office action for a list Acknowledgment is made of a claim for domest ince a specific reference was included in the first 7 CFR 1.78.  1) The translation of the foreign language process the company of the foreign language process acknowledgment is made of a claim for domest reference was included in the first sentence of the company of the foreign language process acknowledgment is made of a claim for domest reference was included in the first sentence of the company of the foreign language process.   | ts have been received. Its have been received in Applicationity documents have been received in (PCT Rule 17.2(a)). If the certified copies not received ic priority under 35 U.S.C. § 119(a) st sentence of the specification of the covisional application has been received in priority under 35 U.S.C. §§ 120 | ion Noed in this National Stage ed. e) (to a provisional application in an Application Data Shee seived. e and/or 121 since a specific |   |  |  |  |
| Attachmen   | t(s)   |   |  |   |  |  |  |
| 2) Notic  | ce of References Cited (PTO-892)<br>ce of Draftsperson's Patent Drawing Review (PTO-948)<br>mation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u>   | 5) Notice of Informal F   | (PTO-413) Paper No(s) Patent Application (PTO-152)   |   |  |  |  |

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### **DETAILED ACTION**

In view of the Appeal Brief filed on October 10, 2003, PROSECUTION IS
 HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
  - (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

## **Priority**

2. Please note that applicant is getting the effective filling date of Patent No. 6,203,525, filed on October 30, 1997 and not from Patent No. 6,332,880, since Patent ('525) is a C-I-P of ('880). The current application and patent ('525) contain new claimed subject matter that is not disclosed in ('880).

## Claim Rejections - 35 USC § 102

- 3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
  - A person shall be entitled to a patent unless -
  - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States



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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-12, 15-23, 27-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Whayne et al (US 6,071,279).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

4. Whayne discloses a catheter assembly (figs. 1 and 53) having a handle 18 with a strain relief element 68,336, an elongate catheter body 12,274, a control element 334 secured to the strain relief element 336, and an apparatus (36,26 or 304).

## Claim Rejections - 35 USC § 103

5. Claims 13, and 24-26 are rejected under 35 U.S.C. 103(a) as being obvious over Whayne et al in view of Brennen et al (US 5,439,006).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

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in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

6. Whayne discloses the invention substantially as claimed. However, Whayne fails to disclose the control element being secured to the strain relief element by a substantially tubular member that surrounds respective portions of the strain relief element and the control element.

Brennen teaches a handle assembly (fig 3) where the control element 12 is secured to the strain relief element 34 by a substantially tubular member 42 that surrounds respective portions of the strain relief element and the control element 12. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Brennen's handle assembly with the Whayne's catheter assembly. Doing so would have manipulated the control element of the catheter assembly.

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## Allowable Subject Matter

7. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Response to Arguments

- 8. Applicant's arguments filed October 10, 2003 have been fully considered but they are not persuasive.
- 9. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen* 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); Intervet *America Inc. v. Kee-Vet Lab. Inc.*, 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed. Cir. 1989).
- 10. In response to applicant's arguments that the interpretation of the phrase "strain relief element" is unreasonable because (1) it is inconsistent with the specification of the present application and (2) it is inconsistent with the meaning given to the term "strain relief" on other catheter patents, the examiner disagrees. An operator using Whayne's steering mechanism 68 (strain relief element) causes to strain and release the strain of the wire, by applying forces on the proximal end of the wire due the action of the steering mechanism 68. The broadest reasonable interpretation has been given to the phrase "strain relief element" in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of

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definitions or otherwise that may be afforded by the written description contained in applicant's specification. Pursuant to 35 USC 112, 2nd paragraph, [I]t is applicant's burden to precisely define the invention, and not the [examiner's]." See In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-29 (Fed. Cir. 1997). Therefore, it would not be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the applicant in the written description.

Furthermore, it would not be proper for the examiner to allow a claim and issue the application with an examiner's statement of reasons for allowance setting forth the special definition given to the words of the claim when no such special definition has been defined by the applicant in the written description.

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- 11. There is one exception, and that is when an element is claimed using language falling under the scope of 35 U.S.C. 112, 6th paragraph (often broadly referred to as means or step plus function language). In that case, the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (See MPEP § 2181- § 2186). The examiner suggests the use of means-plus-function language to give full weight to the specification meaning.
- 12. Moreover, since the **enlightenment** by way of definitions can be used for interpretation of the claim language, the examiner included with this office action **definitions** of the words "strain" and "relief" to support the examiner's point of view.

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The phrase "strain relief element" is a descriptive word and does not impart any specific <u>structure</u> (in the claims) since has not being well described <u>structurally</u> and functionally in the claims with respect and in combination to the other elements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

January 9, 2004

Cris L. Rodriguez

Examiner Art Unit 3763

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## strain1

#### strain (strān) verb

#### strained, strain-ing, strains verb, transitive

- 1. To pull, draw, or stretch tight: strained the sheets over the bed.
- 2. To exert or tax to the utmost: straining our ears to hear.
- 3. To injure or impair by overuse or overexertion; wrench: strain a muscle.
- 4. To stretch or force beyond the proper or legitimate limit: strain a point.
- 5. To alter (the relations between the parts of a structure or shape) by applying an external force; deform.
- 6. a. To pass (gravy, for example) through a filtering agent such as a strainer. b. To draw off or remove by filtration: strained the pulp from the juice.
- 7. To embrace or clasp tightly; hug.

#### verb, intransitive

- 1. To make violent or steady efforts; strive hard: straining to reach the finish line.
- 2. To be or become wrenched or twisted.
- 3. To be subjected to great stress.
- 4. To pull forcibly or violently: The dog strained at its leash.
- 5. To stretch or exert one's muscles or nerves to the utmost.
- 6. To filter, trickle, or ooze.
- 7. To be extremely hesitant; balk: a mule that strained at the lead.

#### noun

- 1. a. The act of straining. b. The state of being strained.
- 2. a. Extreme or laborious effort, exertion, or work. b. A great or excessive pressure, demand, or stress on one's body, mind, or resources: the strain of managing both a family and a career.
- 3. A wrench, twist, or other physical injury resulting from excessive tension, effort, or use.
- 4. Physics. A deformation produced by stress.
- 5. An exceptional degree or pitch: a strain of zealous idealism.

[Middle English streinen, from Old French estreindre, estrein-, to bind tightly, from Latin stringere.]

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# re·lief

#### re·lief (rǐ-lēf') noun

- 1. The easing of a burden or distress, such as pain, anxiety, or oppression.
- 2. Something that alleviates pain or distress.
- 3. a. Public assistance. b. Aid in time of danger, especially rescue from siege.
- 4. a. Release from a post or duty, as that of sentinel. b. One who releases another by taking over a post or duty.
- 5. A pleasant or amusing change; a diversion.
- 6. a. The projection of figures or forms from a flat background, as in sculpture, or such a projection that is apparent only, as in painting. b. A work of art featuring such projection. Also called *relievo*.
- 7. Geology. The variations in elevation of an area of the earth's surface.
- 8. Distinction or prominence due to contrast: "The light brought the white church . . . into relief from the flat ledges" (Willa Cather).
- 9. Law. Redress awarded by a court.
- 10. A payment made by the heir of a deceased tenant to a feudal lord for the privilege of succeeding to the tenant's estate.
- idiom.

on relief

Receiving public assistance because of need or poverty.

[Middle English, from Old French, from relever, to relieve. See relieve. Senses 6, 7, and 8, French, from Italian rilievo. See bas-relief.]

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